REMARKS

Claims 1, 3-11, 14-17, 19, 21-32 and 34-37 are pending. Claims 25-30 have been withdrawn from consideration pursuant to a restriction requirement and have been canceled, without prejudice or disclaimer, by amendment herein. Claim 17 has also been canceled, without prejudice or disclaimer. Thus, claims 1, 3-11, 14-19, 21-24, 31, 32 and 34-37 were examined and were variously rejected under 35 U.S.C. §§ 102 and 103.

By amendment herein, claim 37 has been amended to specify the nature of the vaso-occlusive member, as described throughout the specification as filed. These amendments are made solely to further prosecution and entry thereof is respectfully requested. Applicant reserves the right to file a continuation or divisional application directed to the subject matter of the original claims during the pendency of this application.

In view of the foregoing amendments and following remarks, Applicant respectfully requests reconsideration of pending claims 1, 3-11, 14-16, 19, 21-24, 31, 32 and 34-37 and withdrawal of the remaining rejections.

Rejections Under 35 U.S.C. § 102

Claims 1, 3, 4, 5, 6, 11, 14, 17, 19, 21, 22, 24 and 37 were variously rejected under 35 U.S.C. § 102 as allegedly anticipated by a variety of references. (Final Office Action, paragraphs 2-5). Applicant addresses the rejections in turn.

Rejections Based on Slaikeu

Claims 1, 3, 4, 11, 14, 17, 19, 21 and 24 are rejected under § 102(e) as allegedly anticipated by U.S. Patent No. 6,231,590 (hereinafter "Slaikeu"). Slaikeu is cited for allegedly disclosing a vaso-occlusive composition consisting of a coil and a bioactive material that comprises at least one cytokine such as PDGF, bFGF, VEGF and TGF-beta. (Final Office Action, paragraph 2).

Slaikeu fails to anticipate any of the currently pending claims. As previously noted, it is well settled that claims including fewer elements than contained in the reference are not anticipated by that reference. *See, e.g., Kalman v. Kimberly-Clark Corp.* 218 USPQ 781 (Fed. Cir. 1983), *cert. denied*, 484 US 1007 (1988). Here, pending claims 1, 3, 4, 11, 14, 19, 21 and 24 use the closed transition language "consisting of." Therefore, the pending claims are necessarily limited to the elements listed in the claims and, as such, necessarily **exclude** an inner coating, as required by Slaikeu. Indeed, Slaikeu not only specifies that the vaso-occlusive member have inner and outer coatings, but also requires that the bioactive material be present in the outer

coating. *See, e.g.*, col. 3, lines 12-15 of Slaikeu. The fact that Slaikeu's outer coating may contain a cytokine is utterly irrelevant to the question at hand. What is relevant to determining patentability of the pending claims is the fact that Slaikeu requires the presence of an inner coating (without cytokines), while the claimed invention **never** includes such an inner coating. Accordingly, the claimed compositions and methods always include fewer elements than contained in Slaikeu and, as such, Slaikeu cannot anticipate any of the pending claims.

Rejections Based on Truckai

Claims 1, 5, 6, 19 and 22 stand rejected under 102(e) as allegedly anticipated by U.S. Patent No. 6,458,127 (hereinafter "Truckai"). Truckai is cited for teaching a device comprising a vaso occlusive member and copper. (Final Office Action, paragraph 3).

As repeatedly noted by Applicant, the use of the transition term "consisting of" means that pending claims 1, 5, 6, 19 and 22 are directed to compositions that include only the indicated vaso-occlusive members and indicated bioactive materials. In contrast, Truckai necessarily requires that the vaso-occlusive systems include an elongate catheter sleeve having at least one conductive electrode surface as well as an electrical source. *See, e.g.*, col. 1, lines 10-27 and claim 1. The pending claims **exclude** elements as required by Truckai and, accordingly, this reference does not anticipate the subject matter of claims 1, 5, 6, 19 or 22.

Rejections Based on Kupieki

Claims 1, 7 and 19 stand rejected as allegedly anticipated by U.S. Patent No. 5,669,931 (hereinafter "Kupiecki"). (Final Office Action, paragraph 4). Kupiecki is cited for allegedly disclosing the use of a coil and a thrombus-stabilizing molecule. *Id.*

As noted above, an anticipatory reference must disclose each and every element set forth in the claims. Furthermore, the reference must also enable one of ordinary skill, without undue experimentation, to produce the claimed composition. *See, e.g., Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research*, Fed. Cir. No. 00-1467 (October 1, 2003). Here, pending claims 1, 7 and 19 are directed to compositions consisting of a vaso-occlusive member and, *inter alia,* thrombus-stabilizing molecules. Kupiecki, in contrast, contains a lone reference a "thrombotic" coating. As is known to those of skill in the art, the term "thrombotic" means that the material causes or enhances formation of thrombi. In contrast, the claims are directed to molecules that stabilize existing thrombi. In other words, a material that forms a thrombus does not necessarily stabilize an already existing thrombus, as claimed by Applicant. Therefore, Applicant respectfully submits that Kupiecki fails to describe, teach or

enable the compositions of claims 1, 7 and 19. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection Based on Rand

Claim 37 stands rejected as allegedly anticipated by U.S. Patent No. 4,638,803 (hereinafter "Rand"). Rand is cited for allegedly disclosing a vaso-occlusive composition comprising a vaso-occlusive member of a balloon coated with iron microspheres.

Rand fails to disclose a vaso-occlusive composition as set forth in pending claim 37. In this regard, Rand does not describe the use of balloons in combination with a vaso-occlusive member selected from the group consisting of a coil, a filter, a retention device or combinations thereof. Instead, Rand discloses only the use of coated or uncoated balloons by themselves. Thus, Rand's disclosure of balloons by themselves cannot anticipate pending claim 37.

Rejection Under 35 U.S.C. § 103

The Examiner has also maintained the rejection of claims 8, 9, 10 and 23 as allegedly obvious over Kupiecki. (Final Office Action, paragraph 7). In addition, claim 15 is rejected as allegedly obvious over Kupiecki in view of U.S. Patent No. 5,891,192 (hereinafter "Murayama"). (Final Office Action, paragraph 8). Claim 16 is rejected as allegedly obvious over Kupiecki in view of U.S. Patent No. 6,256,979 (hereinafter "Nikolchev"). Furthermore, claims 31, 32 and 35-36 are again rejected as allegedly obvious over U.S. Patent No. 5,690,666 (hereinafter "Berenstein") in view of WO 00/27445 (hereinafter "Boock"). (Final Office Action, paragraph 10). Finally, claim 34 is rejected as allegedly obvious over Berenstein in view of Boock and in further view of Murayama. (Final Office Action, paragraph 11).

Applicant addresses the rejections in turn.

Rejections Based on Kupiecki

With regard to the rejections based on Kupiecki, Applicant submits, for the reasons detailed above, that this reference fails entirely to disclose compositions or methods involving a thrombus-stabilizing molecule (rather than thrombotic), as presently claimed. For its part, Murayama and Nikolchev also fail to teach vaso-occlusive members as claimed. Therefore, Kupiecki, alone or in combination with Murayama and/or Nikolchev, cannot render pending claims 8, 9, 10, 15, 16 and 23 obvious.

Rejection of Claims 31, 32 and 35-36 based on Berenstein

Claims 31, 32 and 35-36 remain rejected over Berenstein in view of Boock. (Final Office Action, paragraphs 10 and 12). Berenstein is cited for allegedly disclosing a coil and a particulate liquid embolic material while Boock is cited for teaching that a bioactive material is attached to a coil in order to reduce friction. (Final Office Action, paragraph 10). It is alleged that it would have been obvious to provide the composition of Berenstein with the bioactive material of Boock. (Final Office Action, paragraph 10).

As previously noted and acknowledged by the Office, nowhere does Berenstein teach or suggest using a vaso-occlusive composition comprising a vaso-occlusive coil, a liquid embolic material and an additional bioactive material. Nonetheless, the Office asserts that Berenstein somehow suggests combining ultrasoft coil with polymer resins, adhesives or particular materials (col. 5, line 66 to col. 6, line 9) and additional "drugs" (col. 4, lines 42-46). Upon careful reading, however, it is clear that this reference contains absolutely no suggestion that the "drug" be a bioactive material (cytokine; extracellular matrix material; DNA; RNA; functional fragments of DNA, RNA, cytokines or extracellular matrix material; and combinations thereof) as set forth in pending claims 31, 32, 35 and 36. Moreover, there is certainly no suggestion that the drug be attached to the vaso-occlusive member, as required by these claims. Thus, the Examiner's reliance on the term "drug" as allegedly providing the motivation to combine this reference with Boock (or any other reference teaching bioactive materials as set forth in these claims) is entirely misplaced -- there is absolutely no teaching or suggestion in Berenstein regarding either the nature of the drug or that the drug is attached to the coil in any way, merely that it "fills" the interior space. Simply put, Berenstein does not teach or suggest the elements of the pending claims and does not provide the motivation to combine its disclosure with Boock's.

Boock fails to provide what is missing from Berenstein. Not only does Boock require an inner tie layer between the bioactive material and the vaso-occlusive member, it is also completely silent as to particulate liquid embolics set forth in pending claims 31, 32, 35 and 36. Furthermore, as noted above, Berenstein's disclosure of the generic term "drug" would not have lead one to combine disclosures with Boock. The reverse is also true as there is no motivation in Boock to combine its disclosure with Berenstein. Furthermore, even if the disclosures were to be combined, such a combination would not lead to the claimed subject matter because there is no suggestion in either reference that the bioactive material be adsorbed to the vaso-occlusive member, as claimed.

A *prima facie* case of obviousness cannot be established or sustained where there is no suggestion in the references to make the combination. Berenstein's alleged suggestion of using a

drug would not reasonably point one of the skill in the art to Boock's devices in which the bioactive material is attached via a tie layer to the device. The fact that each of the claimed elements were known separately (or even in different combinations), does not change the fact that they were not used in the combination as claimed or, more importantly, that the references suggest combining the elements as claimed. Since there is no motivation to combine the various teachings of Berenstein and Boock and since the combination of these references would not result in the compositions of claims 31, 32, 35 and 36, a *prima facie* case of obviousness cannot be sustained. Accordingly, Applicant requests that this rejection be withdrawn.

Rejection of Claim 34 based on Berenstein

Claim 34 remains rejected as allegedly obvious over Berenstein in view of Boock and in further view of Murayama. (Final Office Action, paragraph 11). Berenstein and Boock are cited as above and Murayama is cited for teaching an absorbable coil device. *Id.*

Applicant submits that there is no combination of these references that would reasonable lead one of skill in the art to the subject matter of claim 34.

For the reasons detailed above, there is no motivation to combine Berenstein's compositions with Boock's bioactive materials and, even if there were, such a combination would not lead to the claimed compositions in which the in which the bioactive material is attached to the vaso-occlusive member. The disclosure of Murayama cannot cure the deficiencies of the combination of Berenstein and Boock. Accordingly, because there is no combination of these references that would lead one of skill in the art to the subject matter of claim 34 and withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing remarks, Applicant believes the claims are in condition for allowance and requests early notification to that effect. If the Examiner believes there are any outstanding issues, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: November 19, 2003

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